510(k) Summary

JUN 0 5 2014

Company: Medyssey Co. Ltd.
148, Sandan-Ro 68 Beon-Gil
Uijeonbu-City
Gyeonggido, Korea
Tel: 82-31-879-0414
FAX: 82-31-879-0415

Contact: John Kuczynski
Vice President of R&D and RA
Medyssey USA, Inc.
1550 E. Higgins Road
Suite 123
Elk Grove Village, IL 60007
Tel: 847-427-0200
FAX: 888-518-9070

Date Prepared: February 3, 2014

Proprietary Name: Medyssey BN Cage

Classification Name: 87 MAX– Orthosis, intervertebral body fusion device, 21 CFR 888.3080, Class II

Predicate Device: The predicate devices include the Medyssey LP Cage (K110067) and the Stryker AVS Spacer (K093704).

Product Description:
The Medyssey BN Cage is designed to provide mechanical support while biologic fusion takes place. The system consists of 105 sizes of implants in zero degrees, 4 degrees and 8 degrees of lordosis. The lordotic angles are bi-convex to accommodate the convexity of the vertebral body above and below the implant. All implants are 9mm wide. Implant lengths range from 22-32mm and the height range from 8-15mm.
The Medyssey BN Cage implants are composed of PEEK Optima LT1 from Invibio. The radiopaque markers are made from Tantalum per ASTM F560.

Indications for Use:
The BN Cage® is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be use with autograft bone.

Brief Discussion of Non-Clinical Tests Submitted:
Mechanical testing of the BN Cage included static axial compression, static compression shear, static torsion, subsidence and dynamic axial compression per ASTM F2077 and ASTM F2267. Test results demonstrated that the BN Cage is equal to or greater than the same test parameters of the predicate devices.

Conclusions from Non-Clinical Tests:
Medyssey concludes that the BN Cage is substantially equivalent to the predicate devices. The areas where the BN Cage is substantially equivalent to the predicate devices include:

- The Indications for Use are exactly the same as the Medyssey LP Cage.
- The material is exactly the same as the Stryker AVS Cage.
- The dimensions are substantially equivalent to the predicate devices.
- The mechanical test results demonstrate the BN Cage is substantially equivalent to the predicate devices.
- The proposed surgical approach is the same as the predicate devices.

Medyssey concludes that any minor differences raise no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2014

Medyssey Company Limited
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K140564
Trade/Device Name: BN Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 4, 2014
Received: March 5, 2014

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140564

Device Name
BN Cage

Indications for Use *(Describe)*
The BN Cage is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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